

REMARKS

Consideration of the amendments and remarks presented herein is respectfully requested. This Amendment is filed within the four-month extended time period for reply; a petition requesting a four month extension of time in which to reply and the associated fee are provided herewith.

I. STATUS OF THE CLAIMS

Claims 1-10, 24, 25, 51, 52, 199, 200, 224-230, 234-237, 239, 240, 242-244 are pending.

Claim 11-23, 26-50, 54-198, 201-223, 231-233, 238, 241, and 245-246 are cancelled.

Of the pending claims, claim 199 is withdrawn.

II. AMENDMENTS

Claim 1 has been amended to more clearly recite the features of the modified glycosaminoglycan. Support for the structure is found in the specification, e.g., in claim 227, and at page 46, lines 1-28. Support for a GAG having a plurality of hydroxyl groups is found on page 19, lines 20-29, as is substitution of hydroxyl groups present within the GAG; support for L¹ and L² is also found on page 46, line 18 to page 47, line 14; support for the degree of substitution is found on page 23, lines 23-32.

Claims 4, 5, and 7 have been amended to conform to the language of newly amended claim 1.

Claim 6 has been amended to recite a particular degree of substitution of GAG-hydroxyl groups, basis for which is found in the specification at page 23, line 25.

Claim 8 recites an L¹ that is an alkylene group. Basis for this amendment is found at page 46, line 26 to page 47, line 8.

Claim 9 recites that L¹ is a methylene, basis for which is found at page 47, line 10.

Claim 24 has been amended to recite that n is 2 or 3; such amendment finds basis at page 22, lines 25-27.

Claim 25 has been amended to recite an L² that is -CH₂CH₂-; support for this amendment is found at page 47, line 10.

Claim 199, currently withdrawn, has been amended to conform to the amendments to claim 1.

Amendments to claims 224-228 are directed to further embodiments encompassed by newly amended claim 1.

Claim 229 finds support in the specification at page 48, lines 25-32.

Claim 234 finds basis in the specification at page 49, lines 6-8.

Claim 235, directed to crosslinking with thiolated collagen or gelatin, finds basis in the specification at page 25, line 11 and at page 59, lines 5-8.

Claims 236 and 237 find basis in the Examples, e.g., at page 100, lines 2-13, and at page 54, lines 20-22.

Amendments to claims not specifically described above are self-evident, and find basis in the specification as set forth above, or are to conform to the language of the newly amended claims or to correct minor word-processing errors.

No new matter has been added to the claims by virtue of the amendments presented herein.

III. REPLY TO RESTRICTION / ELECTION REQUIREMENTS

The Examiner has restricted the claims to one of the following inventions or groups of inventions:

Group I. Claims 1-10, 24, 25, 49-55, 199, 200, and 224-246 drawn to a modified glycosaminoglycan in which at least one hydroxyl group of the structure is modified such that the oxygen atom is covalently bound to a hydrazide-reactive group or an aminoxy-reactive group;

Group II. Claims 14 and 45-57, drawn to a method of making a modified glycosaminoglycan;

Group III. Claim 61, drawn to a method of producing a crosslinked glycosaminoglycan;

Group IV. Claims 201 and 202, drawn to a method for improving wound healing; and

Group V. Claim 203, drawn to a method for delivering living cells to a patient.

Applicant elects the claims of **Group I** to commence prosecution, without traverse.

The Examiner has further required the Applicant to elect a single disclosed species, or a single grouping of species, to commence prosecution on the merits.

To commence prosecution, Applicant elects the following:

a. VARIOUS REACTIVE GROUPS: Applicant elects the reactive group recited generally in claim 227 as set forth in structure (III). The instant claims as currently amended are in keeping with such election.

Should election of a particular reactive group be required to commence prosecution, the Applicant elects L² as equal to -(CH₂)₁₋₁₀ (as recited in claim 10), or should a single particular reactive group be required, Applicant elects -(CH₂)₂- (claim 25); for the variable, L¹, Applicant elects an alkylene group (as recited in claim 8), or should a specific functional group be required, Applicant elects "CH₂" (as recited in claim 9), and Q as equal to -SH (thiol).

b. ADDITIONAL COMPONENTS IN THE PHARMACEUTICAL COMPOSITION: Applicant elects living cells as recited in claim 200.

c. USE CLAIMS: The "use" claims have been amended to conform to U.S. practice.

Claims encompassing the elected species include claims 1-10, 24-53, 200, 224, 225, 226, 229, 230, 234, 235-237, 239, 240, 242, 243, and 244.

It is the Applicant's understanding that Applicant will be entitled to consideration of claims directed to additional species which depend from or otherwise require all limitations of an allowable generic claim as set forth on page 7 of the instant Office action, third paragraph.

IV. EXAMINER'S CHARACTERIZATION OF CLAIMED SUBJECT MATTER

In the Office action requiring restriction of the claimed subject matter dated April 26, 2010, the Examiner has commented on the "technical features" of the claims and asserted that the claims are "*prima facie obvious*" over certain prior art references. See Office action, page 4, line 1 to page 5, line 10.

Since the outstanding Office action presents no formal rejection of the claims, Applicant is not required to provide formal arguments directed to the Examiner's characterization of the claims as being "*prima facie obvious*", nor is a detailed analysis or are formal arguments provided herein. However, Applicant respectfully traverses the Examiner's assertion of obviousness for at least the following reasons.

Although certain carbohydrates such as those mentioned by the Examiner, such as chitosan and cellulose, are often modified by carboxymethylation (i.e., introduction of a carboxymethyl group), carboxymethylation is used to increase the limited water-solubility of polymers such as chitosan or cellulose, to thereby improve their suitability for use in both pharmaceutical and non-pharmaceutical applications. Importantly, the carboxymethylation of cellulose introduces carboxylic acid groups that would otherwise not be present, to allow further chemical derivatization. In contrast, GAGs such as hyaluronan, are water-soluble, thus requiring no additional chemical modification for this purpose. Modification to introduce solubility-enhancing functionalities is unnecessary; thus, given the numerous functional groups inherently present in GAGs such as hyaluronan, i.e., carboxyl groups, along with the molecules' solubility, there is no reason/motivation to introduce additional carboxyalkyl groups into the parent GAG.

By introducing the additional, more chemically-reactive carboxylic acid groups present in the carboxymethyl modification, the inventors provided a means for chemical modification of the newly-introduced carboxylates while minimizing modification of the extant glucuronic acid carboxylates. As a result, the Applicant's claimed modified GAGs were found to possess unexpectedly superior properties over materials prepared from non-carboxymethylated starting materials - see, e.g., Figure 7.

V. CONCLUSION

In view of the foregoing, Applicant respectfully submits that this reply is fully responsive, and that the claims are now in condition to commence prosecution on their merits, since the Applicant has provided (i) an election of species in concert with the elections requested by the Examiner, and (ii) identification of claims encompassing the elected species.

The issuance of a first Office action on the merits of the claims of Group I is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 590-1918.

Respectfully submitted,
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Date: September 27, 2010

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